UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF JOINT MOTION TO EXCLUDE OPINIONS OF KALIOPI PANAGOS, PHARM.D., R.Ph.

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INTRODUCTION

Plaintiffs' Opposition [ECF 2088] ("Opp.") fails to refute Defendants' arguments that the opinions Dr. Kaliopi Panagos seeks to offer in support of Plaintiffs' motion to certify a class of third-party payors ("TPPs") are unreliable, not the product of any relevant expertise, not the proper subject of expert testimony, and do not "fit" the facts here.

First, Plaintiffs do not seriously attempt to demonstrate that Dr. Panagos's opinions are based on any methodology, much less a reliable one. Instead, they argue that Dr. Panagos is rendering an opinion on a non-scientific subject and therefore need not apply any methodology, but can instead just rely on her twenty years as a pharmacist and consultant. Plaintiffs are incorrect. Dr. Panagos's opinions all hinge on her unsupported determination that the valsartan-containing drugs ("VCDs") at issue were no longer bioequivalent to their respective reference listed drugs ("RLDs"). That determination unquestionably requires a scientific analysis, which she simply has not performed. Dr. Panagos (who did not identify any of the bases for her opinions in her report or at her deposition) failed to undertake that exercise in even a rudimentary way, which requires exclusion of her opinions. Moreover, Plaintiffs still do not identify any reliable support for Dr. Panagos's ultimate conclusion (based on her unsupported scientific bioequivalence determination) that, due to a purported false "warranty" the VCDs should not have been included on a

drug formulary and should not have been reimbursed by any TPPs.

Second, even if Dr. Panagos were rendering non-scientific opinions that did not require application of a reliable methodology, Plaintiffs have not shown that she is even qualified to give those opinions (i.e., that she has the necessary specialized knowledge regarding her areas of testimony). Plaintiffs attempt to cast Dr. Panagos as a quasi-regulatory expert, but fail to grapple with her lack of relevant FDA-related experience. And Plaintiffs do not explain how Dr. Panagos's experience as a "pharmacist, consultant on pharmacy benefits, and college of pharmacy faculty member" qualifies her to opine on the inner-workings of TPPs' and Pharmaceutical and Therapeutics ("P&T") committees' creation of a drug formulary. In short, Plaintiffs fall far short of demonstrating that Dr. Panagos has the *relevant* qualifications to opine on the highly specialized topics discussed in her report.

Third, Dr. Panagos's improper regulatory and legal conclusions are not appropriate subjects of expert testimony, and Plaintiffs offer no legitimate basis to admit them. Although Plaintiffs argue that Dr. Panagos's opinions about bioequivalence and warranties are admissible because she does not opine on the ultimate question of whether Defendants actually *complied* with FDA regulatory processes, Dr. Panagos's report and deposition testimony demonstrate that she did just that, as well as interpret legal conclusions that are within the province of the court. Plaintiffs also attempt to salvage Dr. Panagos's "warranty"-related opinion by

asking the Court to simply replace the term "warranty" (*which Dr. Panagos wrote in her own report and used in her deposition testimony*) for the (presumably less "legal conclusion"-sounding) term "representation." The law is clear that a plaintiff cannot salvage its expert's opinions by attempting to rewrite them; notwithstanding Plaintiffs' improper attempt to re-cast them, Plaintiffs cannot avoid the fact that Dr. Panagos's opinions, at bottom, are impermissible conclusions concerning regulatory compliance and opinions as to ultimate legal issues.

Finally, Plaintiffs fail to refute Defendants' argument that Dr. Panagos's opinions concerning TPPs' payment of VCDs will not be helpful to the trier of fact because they merely parrot information within Plaintiffs' pleading. Although Plaintiffs argue that Dr. Panagos's opinion would "aid" the jury in determining the kinds of information that P&T Committees and TPPs relied on when placing the VCDs on the formulary, they ignore that Dr. Panagos offers nothing to the factfinder beyond what is already in the Complaint, and that she could not identify any TPPs in the purported class who took any type of action in response to the voluntary recall.

For these reasons and those stated in Defendant's Joint Motion to Exclude [ECF 2034-1] (the "Motion" or "Mot."), Dr. Panagos's opinions should be excluded.

ARGUMENT

I. DR. PANAGOS COULD NOT IDENTIFY ANY SUPPORT FOR HER OPINIONS.

A. Dr. Panagos Employed No Methodology.

As explained in the Motion, Dr. Panagos's opinions are inadmissible because they are not rooted in any supporting standards, literature, or data, and are therefore unreliable. (Mot. at 8–10.) Plaintiffs insist that Dr. Panagos's opinions should be considered reliable based on her experience alone. Not so. Her entire report turns on her core opinion that the presence of NDMA and/or NDEA resulted in Defendants' VCDs no longer being bioequivalent to the RLD. (ECF 2043-3 (hereinafter, "Report") ¶ 59; ECF 2043-4 (hereinafter, "Panagos Dep.") at 183:10–184:3.) That bioequivalence determination cannot be made without a scientific analysis, and Plaintiffs' claim that she does not *need* a methodology is essentially a concession that she *has not applied* one. Dr. Panagos's experience simply has no bearing on whether her opinions are based on a reliable scientific methodology; those are two "distinct concepts" that the district court "must take care not to conflate." *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (*en banc*); *see also id.* at 1261 ("If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.").

Plaintiffs' cases are not to the contrary. Those cases merely recognize that

concepts such as peer review, publication, potential error rate, and the like may not apply in certain *non*-scientific cases—for example, where an expert who has been in the glass business for nearly four decades seeks to opine that the very kind of glass he has worked with in his profession has not been properly maintained. *See States v. Fernwood Hotel & Resort*, Case No. 12-0906, 2014 WL 198568, at *1–4 (M.D. Pa. Jan. 15, 2014); *see also U.S. v. Schiff*, 538 F. Supp. 2d 818, 845 (D.N.J. 2008) (allowing expert to opine "on what information is important to a reasonable investor" based on his "experience in investing client assets and valuing companies").

Moreover, even in Plaintiffs' *non*-scientific cases, the opinions were grounded in some kind of methodology—for example, an expert's "own primary field research" in which he "conduct[ed] observations and interviews on the ground" that formed the basis for his opinion. *U.S. v. Vaghari*, 735 F. Supp. 2d 197, 204 (E.D. Pa. 2010); *see also Schiff*, 538 F. Supp. 2d at 845 (noting that expert "cites to analyst reports for corroborating evidence of his opinions regarding what information is important to investors").[1]

Here, by contrast, Dr. Panagos seeks to offer opinions about the FDA, bioequivalence, nitrosamines, valsartan, and warranties—all of which implicate

[1] *Berry v. City of Detroit*, 25 F.3d 1342 (6th Cir. 1994)—a civil rights action alleging wrongful death by a police officer—is even more inapposite. In that case, the Sixth Circuit held that the expert "did not have the qualifications to testify" that the alleged failure to properly discipline officers was the proximate cause of the shooting, "and, if he did, no proper foundation was laid for his ultimate opinion." *Id.* at 1348.

complex scientific and regulatory questions. And she attempts to do so without providing *any* basis either in her report or deposition testimony. Indeed, the closest Plaintiffs come to attempting to show otherwise is citing to testimony by Dr. Panagos in which she provided a laundry list of sources (e.g., the American Journal of Managed Care, the Journal of Managed Care, and the Orange Book) as forming the basis for her statements in Paragraphs 19 and 20 of her report. (Opp. at 5 (citing Panagos Dep. 99:22–100:6).) Needless to say, a list of sources without more does not "explain precisely how [the expert] went about reaching [her] conclusions[.]" *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995).

B. Dr. Panagos's Experience Cannot Compensate for Her Lack of Methodology.

Even if experience alone could serve as the sole metric for reliability of her opinions, neither Plaintiffs nor Dr. Panagos have explained *how* Dr. Panagos's experience as a pharmacist sufficiently qualifies her to render her opinions, let alone how her experience is sufficient to serve as the only basis for reliability of her opinions. (*See* Panagos Dep. at 52:15–21, 65:20–21, 79:3–5, 172:22–24.) Their failure to do so further demonstrates the inadmissibility of her opinions. *See* Fed. R. Evid. 702, Advisory Committee Notes (2000) ("If [a] witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and

how that experience is reliably applied to the facts.")[2]

Dr. Panagos has no experience evaluating the bioequivalence of generic and reference listed drugs, engaging in the FDA drug approval process, or determining which drugs should be included (or how they should be rated) in the Orange Book.[3] (*See* Mot. at 18–19.) In short, Plaintiffs' attempt to dilute the Rule 702 standard should be rejected, and all of Dr. Panagos's opinions should be excluded for lack of a reliable methodology.

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[2] *See also Ruggiero v. Yamaha Motor Corp.*, Case No. 15-49 (JBS/KMW), 2017 U.S. Dist. LEXIS 48908, at *14 (D.N.J. Mar. 31, 2017) (same); *Lowery v. Sanofi-Aventis LLC*, No.: 7:18-cv-00376, 2021 WL 872620, at *7 (N.D. Ala. Mar. 9, 2021) (same).

[3] Plaintiffs (citing *Berry,* 25 F.3d 1342) unavailingly analogize Dr. Panagos to a beekeeper whose opinions about flight principles of a bee could be admissible, without having applied any scientific principles. Plaintiffs overlook that this depends on the opinion ("bumblebees always take off into the wind"—an observation which does not require any particular technical or scientific training) and (importantly) the existence of a proper foundation for the opinion (the beekeeper's firsthand observations, having "seen a lot more bumblebees than [the jurors] have"). *Id*. at 1350. In keeping with Plaintiffs' proposed analogy, Dr. Panagos hasn't seen enough bumblebees, and she seeks to opine on far more than what direction they take off into. *See also Wells Fargo Bank, N.A. v. HoldCo Asset Mgmt., L.P.*, Case No. 16-cv-6356, 2017 U.S. Dist. LEXIS 106969, at *36–39 (S.D.N.Y. July 11, 2017), *aff'd on other grounds*, 729 F. App'x 124 (2d Cir. July 6, 2018) (excluding opinions on collateralized debt obligation (CDO) liquidations despite proposed expert's "11 years of experience" "working in the CDO markets, including CDO liquidations" where "her actual involvement in CDO liquidations [wa]s seemingly limited to her work marketing, selling and facilitating trades in various CDOs from 2012 to 2014" and she did "not describe how many liquidations she has been involved in and what, beyond 'trade execution and client advis[ing],' her role entailed").

C. Plaintiffs' Other Attempts at Establishing Reliability Also Fail.

Plaintiffs' additional arguments as to the reliability of Dr. Panagos's FDA-related opinions are likewise unavailing. As established in the Motion, Dr. Panagos opines on whether generic valsartan is bioequivalent to the RLD for purposes of its inclusion in the FDA-published Orange Book, without fully understanding the FDA definition of bioequivalence. (Mot. at 13–14.) Plaintiffs dispute that Dr. Panagos lacks familiarity with the FDA's definition (Opp. at 7), but "understand[ing] what 'bioequivalence' means in her profession" is not the same as understanding the FDA definition of the term; her expert report does not contain the definition of "bioequivalence" that is set out in the Code of Federal Regulation; and her wavering testimony by no means "clearly" indicates that she reviewed that definition when drafting her report. (*See* Mot. at 13–15 (expanding upon these points); Panagos Dep. at 171:15–184:3.)

Next, Plaintiffs do not disagree that Dr. Panagos did not independently analyze or review existing data regarding the presence and/or levels of NDMA or NDEA in the RLD and/or the VCDs prior to rendering a bioequivalence opinion. Instead, they maintain that because Dr. Panagos is "explaining and applying basic concepts in her field" and stating "uncontroversial scientific fact[s]," she did not need to do her own research or review literature. (Opp. at 8–10.) Plaintiffs miss the point. Underlying Dr. Panagos's bioequivalence opinion are claims that the VCDs

at issue contained NDMA and/or NDEA whereas their respective RLDs did not (or, at a minimum, that the VCDs contained different levels of NDMA and/or NDEA than did the respective RLD), thus purportedly destroying "sameness" among them. (Report ¶ 59.) Yet Dr. Panagos never even bothered to check whether anyone had ever tested the RLD for NDMA and/or NDEA, and thus could not possibly know whether it contained NDMA and/or NDEA and in what amount. The problem with Dr. Panagos's opinions isn't that she failed to do one particular thing or another—it's that she failed to do anything at all to ensure their reliability.

Finally, responding to the unreliability of Dr. Panagos's opinions "on the FDA's decision to include a generic drug in the Orange Book" (Mot. at 12), Plaintiffs contend that Dr. Panagos has the experience to opine upon "P&T committees' and TPPs' reliance on [an] Orange Book listing" (Opp. at 11). This is irrelevant: Plaintiffs do not explain how Dr. Panagos has expertise regarding the FDA's decision-making process by which it lists and rates generic drugs in the Orange Book to opine that "[t]he 'AB' rating in the FDA Orange Book, based as it is on the generic drug manufacturer's ANDA, represents a manufacturer's warranty to TPPs and P&T Committees for placement on a prescription drug formulary." (Report ¶ 47.)

II. DR. PANAGOS'S REGULATORY OPINIONS ARE NOT A PROPER TOPIC FOR EXPERT TESTIMONY.

Dr. Panagos's FDA-related opinions are also inadmissible because they are impermissible regulatory conclusions. Plaintiffs acknowledge that experts cannot

opine "on whether the defendant has complied with [legal] duties." (Opp. at 16 (citation omitted).) But Dr. Panagos does just that. Despite Plaintiffs' protestations to the contrary, she opines that FDA approval requires generic manufacturers' demonstration and maintenance of bioequivalence, and then concludes that "[t]he presence of the contaminant rendered the manufacturer defendants' versions of VCDs not equivalent to the branded product." (Report ¶¶ 51, 54, 59.) This is a conclusion about Defendants' regulatory compliance with respect to obtaining and maintaining FDA approval (through bioequivalence)—it goes far beyond simply stating "established industry customs and standards for bioequivalence." (Opp. at 16.) These impermissible opinions must be excluded.

III. DR. PANAGOS'S "WARRANTY" OPINIONS SHOULD BE EXCLUDED DESPITE PLAINTIFFS' ATTEMPT TO RETROACTIVELY REMOVE THE TERM FROM HER REPORT.

A. Dr. Panagos's "Warranty" Opinions Are Unsupported, and Her General Pharmacy Experience Does Not Make Them "Reliable."

Plaintiffs attempt to walk back Dr. Panagos's use of the term "warranty," replacing it with the lay term "representation." (Opp. at 23.)[4] This argument fails too. First, a party cannot defend an expert's opinions by changing them. *See Tamraz*

[4] The concept of a breach of "warranty" is one of the central components of Dr. Panagos's report. Her utter lack of qualifications or ability at deposition to describe how she determined that a drug's listing/rating in the Orange Book equates to a "warranty" (*see* Panagos Dep. at 123:2–128:14) should not now be excused by Plaintiffs' post-hoc attempt to replace the term.

v. Lincoln Elec. Co., 620 F.3d 665, 672–73 (6th Cir. 2010) (rejecting counsel's effort to redefine the expert's opinion through briefing because the "opinion cannot escape its own logic"). Also, Dr. Panagos's opinion—based on her oversimplified concept of bioequivalence as "sameness"—"that the representations Defendants made to the FDA about their VCDs were, due to the contamination, factually incorrect" (Opp. at 20) lacks reliability. Dr. Panagos has no idea what levels of NDMA and/or NDEA were in the RLD, and has no specialized knowledge or experience related to assessing bioequivalence. A new term cannot make these problems go away.

Moreover, contrary to Plaintiffs' assertions (Opp. at 19–22), nothing in Dr. Panagos's pharmacist/consultant background qualifies her to opine on what sort of "representation," if any, is created by a drug listing in the Orange Book, or on whether the presence of "contaminants" renders any "warranty" or "representation" incorrect. Plaintiffs assert that Dr. Panagos is an expert on how the FDA's Orange Book "*is used* and *what it means* in the industry." (*Id.* at 22.) But knowing how pharmacists or TPPs may use the Orange Book does not qualify Dr. Panagos to opine that a drug listing and rating therein serves as a manufacturer's "warranty" or whether any such "warranty" or "representation" was true.[5] (Report ¶¶ 57–59.)

[5] This is in strong contrast to the gastroenterology professor, practitioner, and journal editor in the case cited by Plaintiffs, *Altana Pharma AG v. Teva Pharm. USA, Inc.*, No. 04-2355, 2013 U.S. Dist. LEXIS 74211, at *21–22 (D.N.J. May 14, 2013), who "opine[d] on the interchangeability of [proton pump inhibitors] and on physicians' practices with respect to prescribing [same]," or the expert in *United States ex rel.*

B. Dr. Panagos's "Warranty" Opinions Are Impermissible Legal Conclusions.

Whether Dr. Panagos bases her warranty-related opinions on her subjective understanding of "warranty" or on some similar term (as Plaintiffs now claim), her opinions must be excluded as impermissible legal conclusions. Plaintiffs argue that Dr. Panagos merely provides "a description of how the approval process for the drugs at issue in this case played out." (Opp. at 23.) But Dr. Panagos affirmatively opines that Defendants' alleged warranties were "false." (*See, e.g.*, Report ¶ 57; *id.* §§ VI.I, VI.J.) These opinions plainly go to the ultimate legal/regulatory issue and, therefore, must be excluded. *See, e.g.*, *Hanreck v. Winnebago Indus.*, No. 1:16-cv-01163, 2019 U.S. Dist. LEXIS 51388, at *56 (M.D. Pa. Mar. 27, 2019) (precluding an expert opinion "regarding the breach or interpretation of [a] warranty").

IV. DR. PANAGOS'S LACK OF SUPPORT AND QUALIFICATIONS RENDERS HER OPINIONS REGARDING DRUG FORMULARIES AND TPPs' PAYMENT OF VCDs INADMISSIBLE

A. Plaintiffs Identify No Reliable Support for Dr. Panagos's Blanket Opinion that TPPs Would Not or Should Not Have Paid for VCDs.

Plaintiffs contend that because Dr. Panagos's "opinion is focused on the

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Penelow v. Janssen Prods., LP, Case No. 12-7758, 2022 U.S. Dist. LEXIS 4282, at *30, 33–34 (D.N.J. Jan. 10, 2022), also cited by Plaintiffs, with a "long and storied career in pharmacy administration," including teaching about "reimbursement by private and public prescription programs" and consulting on reimbursement-related matters, who opined on "how CMS makes coverage and reimbursement decisions under Medicare Part D" for certain drugs."

decision TPPs made to place the drug on the formulary *before* the VCD contamination was disclosed," it does not matter what the TPPs did after the recall. (Opp. at 24–25.) This ignores that Dr. Panagos offers the blanket opinion that TPPs who paid for alleged nitrosamine-containing VCDs were all economically injured. To provide reliable support for that opinion, Dr. Panagos needs to have some basis to opine whether all TPPs were economically injured. She has none.

Once again, Plaintiffs argue that Defendants' Rule 702 challenges go to the "weight" of Dr. Panagos's opinions, but the very case Plaintiffs cite for this proposition confirms that there must first be a determination "that a witness is competent to testify as an expert" before "challenges to the expert's skill or knowledge go to the weight to be accorded the expert testimony rather than to its admissibility." (Opp. at 26.) Dr. Panagos does not meet this threshold requirement. Information about her *general* experience "provid[ing] pharmacy benefit consulting," without any *specific* scope, depth, or frequency of her involvement with creating and managing formularies, is not enough to form the sole basis for reliability of her opinions. (*See* Mot. at 32.) Plaintiffs again fail to meet their burden to "explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702, Advisory Committee Notes (2000).

For the same reasons, Dr. Panagos is unqualified to opine on information that

P&T committees or TPPs rely on when placing generic drugs on their drug formularies or reimbursing for the cost of drugs. (*See* Mot. at 32–33.) Plaintiffs fail to rebut this. Although Dr. Panagos refers vaguely to experience "providing pharmacy benefit guidance," (Opp. at 27), her refusal to identify a single TPP or PBM for whom she has worked does not establish—despite her short period of pertinent employment (ten-month tenure at SmithRx, where she set up a formulary)—that she has sufficient experience, familiarity, and/or training regarding TPPs' formulary placement and drug reimbursement to opine on this topic. *See, e.g.*, *O'Conner v. Commonwealth Edison Co.,* 13 F.3d 1090, 1107 n.19 (7th Cir. 1994) (affirming exclusion of physician's expert testimony where he had "limited exposure" (treated five patients with the condition over his twenty year career) to the specific condition he was opining on); *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2000 U.S. Dist. LEXIS 9661, at *47–48 (E.D. Pa. June 28, 2000) (pharmacologist unqualified to opine that fenfluramine causes certain diseases in part due to his "limited experience in examining disease causation in humans"). Plaintiffs essentially just argue "she has the experience" without explaining *what* it is that Dr. Panagos *has actually done* that qualifies her to give her specific opinions. Plaintiffs fail to carry their burden.

B. Plaintiffs Do Not Show that Dr. Panagos's Opinions Regarding TPPs' Payment of VCDs Will Help the Factfinder.

Finally, though she seeks to opine on payments that the TPPs allegedly should not have made due to the purportedly "contaminated" nature of the VCDs, Dr. Panagos failed to identify from any source other than the Complaint any TPPs that paid for a "contaminated" VCD. And, as established in the Motion, Dr. Panagos relies solely on allegations found within the Complaint for purported proof that any TPP sought a refund after paying for an allegedly nitrosamine-containing VCD. Without any information beyond the Complaint, her opinions would be of no use to the trier of fact. (*See* Mot. at 33–35.) Plaintiffs do not meaningfully respond to this in their Opposition, and fail to show that Dr. Panagos's opinions concerning the propriety of TPPs' payment of VCDs in fact would be helpful to the factfinder.

CONCLUSION

For these reasons, and those discussed in Defendants' Motion, Defendants respectfully request that the Court exclude Dr. Panagos's opinions in their entirety.

Dated: June 16, 2022

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CERTIFICATE OF SERVICE

I, Kate Wittlake, an attorney, hereby certify that on June 16, 2022, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Kate Wittlake
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